

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875
THIS DOCUMENT RELATES TO ALL CASES	HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK)

**PLAINTIFFS’ MOTION TO AMEND/CORRECT REVISED *DAUBERT*
ORDER AS TO OPINIONS OF TEVA LIABILITY EXPERT
TIMOTHY ANDERSON (ECF 2610)**

Plaintiffs reluctantly file this motion to amend/correct the revised *Daubert* order as to the opinions of Teva liability expert Timothy Anderson (ECF 2610). Plaintiffs conferred with Teva about the relief requested in this motion, but Teva did not agree in any respect.

I. OVERVIEW OF ISSUE

On January 5, 2024, this Court precluded most of the opinions by one of Teva’s liability experts, Mr. Timothy Anderson. *See* ECF 2581, 2582. Among other things, the Court found that Mr. Anderson “cited no reliable methodology,” proffered improper “legal opinion[s],” inappropriately implied he was an expert in legal regulatory interpretation, and was a self-professed “expert reader” of cGMPs and industry guidance. *See* ECF 2581 at 8-9. Specifically, the Court ***precluded all***

of Mr. Anderson's opinions *except* 14 paragraphs pertaining to general regulatory background. *Id.* All of these rulings were proper.

On January 17, 2024, Teva filed a motion "to amend/correct" this Court's *Daubert* ruling as to Mr. Anderson, *see* ECF 2592, but never vetted its concern with Plaintiffs before filing its motion. Teva did not ask this Court to re-think its substantive rulings in any way. Rather, Teva simply asserted that the illustrative paragraphs cited in the Court's *Daubert* ruling were to Mr. Anderson's prior class certification report, not to paragraphs in his operative liability report.¹

Before Plaintiffs could file their response to Teva's motion, this Court granted the motion in part, and issued an amended *Daubert* order as to Mr. Anderson. *See* ECF 2610. The amended order did not modify the prior order's discussion of Mr. Anderson's flawed methodologies or other shortcomings. Rather, the amended order simply cites paragraphs from Mr. Anderson's liability report that were precluded.

However, the amended order (ECF 2610) appears to overlook many paragraphs in the liability report which are nearly identical to paragraphs the Court

¹ Plaintiffs never attached Mr. Anderson's earlier class certification report to any of their *Daubert* papers. Plaintiffs only attached Mr. Anderson's operative liability report, dated December 19, 2022, as Exhibit 1 to Plaintiffs' *Daubert* motion (*see* ECF 2297). Teva appears to have attached Mr. Anderson's class certification report, dated January 12, 2022, as Exhibit A to its opposition to the *Daubert* motion (*see* ECF 2337). This may be the source of the confusion. Plaintiffs note Teva did not bother to attach either report to its motion to "amend/correct."

precluded from the class certification report (this is discussed more *infra*). It also does not preclude some paragraphs that Teva's own motion to amend/correct conceded should be precluded given the Court's initial reasoning.

At the February 1, 2024 CMC, the Court told the parties to meet and confer. On February 8, 2024, Teva told Plaintiffs that they believe the amended order (ECF 2610) completely supersedes the prior order (ECF 2581 & 2582), including the Court's underlying analysis and rationale for precluding the vast majority of Mr. Anderson's opinions (most of which he carries over from his class report to his liability report) the first time. Teva would not agree to any of the relief sought in this motion.

Plaintiffs, therefore, reluctantly move to amend/correct the revised *Daubert* order (ECF 2610) to ensure preclusion of additional paragraphs from Mr. Anderson's liability report. Plaintiffs do not re-argue or rehash any substantive *Daubert* arguments. Rather, Plaintiffs confine this motion to identifying additional paragraphs in Mr. Anderson's liability report which ought to be precluded because they track, nearly verbatim, paragraphs in his class report which this Court explicitly precluded the first time. Further, because Mr. Anderson's liability report purports to "incorporate" the entirety of his class report, Plaintiffs submit that the Court's original *Daubert* ruling as to Mr. Anderson should stand (i.e., precluding all but 14 paragraphs of his class report).

II. The Court’s Original *Daubert* Opinion

The Court fully analyzed Mr. Anderson’s opinions and the bases therefore (albeit those in his class report), and found them wanting. The Court found, *inter alia*, that Mr. Anderson lacked a reliable methodology for his “review of Teva’s reviews” (i.e., Mr. Anderson looked at Teva’s audits of ZHP); he improperly compared “his interpretations of the cGMPs with his interpretation of Teva’s [procedures]”; and he lacked a “transparent explanation of his methodology.” ECF 2581 at 7-8 (emphasis original). On top of that, Mr. Anderson improperly “opines that Teva adopted the industry standard of NOT independently verifying the information in API suppliers’ reports.” *Id.* at 8. Mr. Anderson’s views about “compliance with ‘industry standards’ constitutes a legal opinion as to negligent or diligent conduct, a conclusion Anderson is not qualified to make and which is not helpful to the fact-finder.” *Id.*

These same shortcomings bar Mr. Anderson’s opinions at trial, whatever the report in which Mr. Anderson expressed them.

III. Mr. Anderson’s “Incorporated By Reference” Class Certification Opinions Should Remain Precluded

Mr. Anderson’s liability report purports to “specifically incorporate by reference” his class certification report. While such bootstrapping is debatable to begin with, the Court’s original *Daubert* ruling specifically ***precluded all but 14 paragraphs*** from Mr. Anderson’s class certification report:

As the precluded liability opinions are intertwined throughout Anderson's report, **ONLY** the opinions in the following paragraphs of Anderson's report are **NOT PRECLUDED**: ¶¶ 30 - 43.

ECF 2581 at 9. For clarity at trial, the Court should re-affirm that Mr. Anderson's class certification report opinions are precluded (except ¶¶ 30-43, per ECF 2581).

IV. The Court Should Preclude Mr. Anderson's Liability Opinions That Teva's Own Motion Suggested For Preclusion

Teva's motion to amend/correct (ECF 2610) identified numerous paragraphs in Mr. Anderson's liability report that Teva itself asserted should be precluded based on the Court's original *Daubert* analysis. These paragraphs are as follows:

<u>Paragraphs Teva's Motion Suggested For Preclusion (ECF 2592 at 3)</u>	<u>Precluded in Court's Amended <i>Daubert</i> Order (ECF 2610)?</u>
¶ 20	Yes
¶ 21	Yes
¶ 22	Yes
¶ 28	No
¶ 29	No
¶ 78	No
¶ 90	No
¶ 101	No
¶ 120	No
¶ 130	No
¶ 190	No
¶ 213	No
¶ 222	Yes
¶ 223	No
¶ 224	No

Plaintiffs agree with Teva. The Court should preclude ¶¶ 28, 29, 78, 90, 101, 120, 130, 190, 213, 223, and 224 of Mr. Anderson’s liability report based on the Court’s original *Daubert* analysis and Teva’s recommendation.

V. The Court Should Preclude Mr. Anderson’s Liability Opinions That Are Nearly Identical to His Precluded Class Opinions

The Court specifically precluded *all but 14 paragraphs* (out of 182 total paragraphs, plus a lengthy appendix) from Mr. Anderson’s class certification report. The only paragraphs the Court did not preclude solely relate to “background” about the FDA’s regulation of drugs, and the dates of ANDA approvals for the at-issue Teva VCDs.

Mr. Anderson’s two reports are largely identical. In fact, Mr. Anderson’s liability report cuts-and-pastes large swathes from his class certification report.² For instance, the Court specifically precluded ¶ 24 of Mr. Anderson’s class certification report, but now Teva contends that Mr. Anderson can freely testify to nearly identical opinion expressed in ¶ 32 of his liability report. But look at these two paragraphs side-by-side:

[see overleaf]

² Some paragraphs even carry-over the same typos or capitalization inconsistencies.

Examples of Paragraph the Court Precluded from Mr. Anderson's Class Certification Report	Non-Precluded Paragraph That Appears in Mr. Anderson's Liability Report
<p>24. [REDACTED]</p>	<p>32. [REDACTED]</p>

Plaintiffs have carefully compared Mr. Anderson's class and liability reports. They believe the following paragraphs in his liability report should be precluded because, in addition to those already identified by the Court's amended *Daubert* order (ECF 2610), they are nearly identical to precluded paragraphs from Mr. Anderson's class report. Notably, a lot of Mr. Anderson's precluded class certification opinions are no longer germane because he attempted to rebut Plaintiffs' class expert, Mr. Johnathan Quick, whereas Plaintiffs' presented different cGMP experts at the liability phase. The few additional preclusions should include:

<u>Precluded Paragraph in Mr. Anderson's Class Report</u>	<u>Corresponding, Non-Precluded Paragraph in Mr. Anderson's Liability Report</u>
¶ 24	¶ 32
¶¶ 28, 65	¶ 29 (specifically citing back to ¶¶ 28 and 65 of his class report)

Appendix, “All the Information in Tables on pages 36 to 38” (reviews of Malta Health Authority or FDA inspections)	Appendix at pages 90 to 98 (reviews of Malta Health Authority or FDA inspections)
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In addition, the Court previously precluded all Mr. Anderson’s “review of reviews” (ECF 2581 at 8). That is, the Court specifically held that Mr. Anderson “never specifies whether he has looked at a sample or all of Teva audits of the regulators’ or suppliers’. Again, this points to a lack of reliable methodology.” The Court continued: “Anderson has set up no independent yardstick of factors, criteria, checkpoints that would provide even an ordinal analysis as to the reliability of his review of Teva’s ‘reviews’ of ZHP reports. Simply, there is a complete absence of an underlying recognized rationale or literature search or scientific method supporting Anderson’s opinion that Teva’s ‘reviews’ sufficed.” *Id.*

Mr. Anderson offers these same ‘review of reviews’ opinions in his liability report at ¶¶ 190-195 and his appendix (pages 63-98 of liability report). There is no principled basis, and in the meet and confer process Teva cited none, for why the Court’s rationale for precluding a table in Mr. Anderson’s class report should not apply to the exact same table which Mr. Anderson cut-and-pastes into his liability report.

VI. CONCLUSION

In addition to the paragraphs cited in the Court's amended *Daubert* order (ECF 2610), the Court also should preclude Mr. Anderson's class certification report in its entirety except ¶¶ 30-43, as it originally did, because Mr. Anderson's liability report attempts to incorporate his earlier class report entirely. The Court should further preclude the paragraphs of Mr. Anderson's liability report that Teva had said should be precluded (¶¶ 28, 29, 78, 90, 101, 120, 130, 190, 213, 223, 224), as well as paragraphs in his liability report that mirror nearly identical opinions the Court had precluded from his class report (¶¶ 24, 28, 29, 32, 65, 190-195, and appendix).³

Plaintiffs do not wish to burden the Court with superfluous exhibits, but are prepared to re-submit either of Mr. Anderson's reports for the Court's convenience.

Dated: February 12, 2024

Respectfully submitted,

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³ Paragraphs 28, 29, and 90 should be precluded both because Teva identified them originally in its motion, and they also are nearly identical to previously precluded paragraphs in Mr. Anderson's class report.

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CERTIFICATE OF SERVICE

I hereby certify that on February 12, 2024, a true and correct redacted copy of the foregoing was filed and served via the Court's CM/ECF system, and an undredacted version was served on the court and the Defense Executive Committee via email.

/s/ David J. Stanoch

David J. Stanoch